SmartPA Criteria Proposal

Drug/Drug Class:	Biguanides & Combination Agents PDL Edit
First Implementation Date:	April 13, 2005
Revised Date:	October 1, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Type 2 diabetes mellitus is a significant health problem associated with excessive morbidity and mortality. As the prevalence of this metabolic disorder is rapidly increasing and as older treatments fail to stabilize the disease in many participants, prevention and control are considered key objectives. Metformin monotherapy and combination therapy are generally well tolerated and improve glycemic control and lipid concentrations in patients with non-insulin-dependent diabetes mellitus, whose diabetes is poorly controlled with diet or sulfonylurea therapy alone. Metformin decreases hepatic glucose output by inhibiting gluconeogenesis by reducing glucose substrate availability through its antilipolytic effect which decreases serum free fatty acid concentrations. It also increases insulin-mediated glucose use in peripheral tissues such as in the muscle and liver, typically after meals. In addition, metformin also activates the AMP-activated protein kinase (AMPK) enzyme in hepatocytes which contributes to decreases serum lipid concentrations. The most common adverse effects are gastrointestinal related, metallic taste, vitamin B12 deficiency, and lactic acidosis. It is recommended to take these agents with meals to reduce gastrointestinal adverse effects.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• **Glipizide/Metformin** • **Glyburide/Metformin** • Metformin HCl • Metformin ER (gen Glucophage XR®)	• Fortamet ER® • Glucophage® • Glucophage XR® • Glumetza® • Metformin ER (gen Fortamet® OSM) • Metformin ER (gen Glumetza® MOD) • Metformin Soln • **Repaglinide/Metformin** • Riomet® • **Riomet ER™**

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List**
☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Biguanides & Combination Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Glumetza and Fortamet: adequate therapeutic trial on generic Glucophage and/or Glucophage XR (90/120 days) **OR**
- **For Riomet ER: Clinical Consultant Review**

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- Claim exceeds maximum dosing limitation for the following:

FORTAMET ER 1,000 MG	METFORMIN ER	2 tablets per day
FORTAMET ER 500 MG	METFORMIN ER	5 tablets per day
GLUCOPHAGE XR 500 MG	METFORMIN ER	4 tablets per day
GLUCOPHAGE XR 750 MG	METFORMIN ER	2 tablets per day
GLUCOVANCE 1.25 MG/250 MG	GLYBURIDE/METFORMIN	1 tablet per day
GLUCOVANCE 2.5 MG/500 MG	GLYBURIDE/METFORMIN	2 tablets per day
GLUCOVANCE 5 MG/500 MG	GLYBURIDE/METFORMIN	4 tablets per day
GLUMETZA ER 1,000 MG	METFORMIN ER	2 tablets per day
GLUMETZA ER 500 MG	METFORMIN ER	4 tablets per day
METAGLIP 2.5 MG/250 MG	GLIPIZIDE/METFORMIN	1 tablet per day
METAGLIP 2.5 MG/500 MG	GLIPIZIDE/METFORMIN	4 tablets per day
METAGLIP 5 MG/500 MG	GLIPIZIDE/METFORMIN	4 tablets per day

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

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5. American Diabetes Association (ADA). Standards of Medical Care in Diabetes-2020. *Diabetes Care.* 2020;43(suppl 1): S1-S212.
6. Evidence-Based Medicine and Fiscal Analysis: “Oral Antidiabetics: Biguanide and Combination Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; April 2020.
7. Evidence-Based Medicine Analysis: “Biguanides”, UMKC-DIC; April 2020.
8. Evidence-Based Medicine Analysis: “Antidiabetic Combination Agents – Oral and Injectable”, UMKC-DIC; March 2020.
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10. Glucophage [package insert]. Princeton, NJ; Bristol-Myers Squibb; 2018.
11. Glumetza [package insert]. Bridgewater, NJ; Salix Pharmaceuticals; 2019.
12. Riomet [package insert]. Cranbury, NJ: Sun Pharmaceuticals; 2018.